

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004D-0193]

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Certifier R. LEDESMA

Draft "Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" dated May 2004. The draft guidance provides to HCT/P establishments recommendations for the appropriate screening and testing of cell and tissue donors for evidence of relevant communicable diseases. These recommendations would assist HCT/P establishments in complying with the requirements for the eligibility determination for donors of HCT/Ps.

DATES: Submit written or electronic comments on the draft guidance by [*insert date 90 days after date of publication the Federal Register*] to ensure their adequate consideration in preparation of the final guidance. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one

self-addressed adhesive label to assist the office in processing your requests. The draft guidance may also be obtained by mail by calling the Center for Biologics and Research Voice Information System at 1-800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

Submit written comments on the draft guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *<http://www.fda.gov/dockets/ecomments>*.

FOR FURTHER INFORMATION CONTACT: Paula S. McKeever, Center for Biologics Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled “Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-based Products (HCT/Ps)” dated May 2004. Because of their nature as derivatives of the human body, HCT/Ps pose a risk of transmitting communicable diseases. For this reason, FDA is publishing a final rule “Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” elsewhere in this issue of the **Federal Register**. These donor-eligibility requirements, which are contained in part 1271 (21 CFR part 1271), subpart C, are part of the minimum requirements applicable both to HCT/Ps regulated solely under these regulations and section 361 of the Public Health Service Act and to those HCT/Ps also subject to regulation as drugs, devices, and/or biological products.

In the draft guidance, FDA is providing recommendations to HCT/P establishments on how to comply with the requirements in 21 CFR part 1271, subpart C. The recommendations address the following topics:

- Elements of the donor eligibility determination, including procedures and recordkeeping;
- Donor screening, including review of risk factors for, and clinical and physical evidence of, relevant communicable diseases;
- Donor testing, including general testing for all HCT/Ps and testing specific for some types of HCT/Ps (e.g., reproductive cells and tissues); and
- Exceptions to donor screening and testing.

The draft guidance would apply to cells and tissues recovered on or after the effective date of the final rule published elsewhere in this issue of the **Federal Register**. Part 1271 also contains other requirements applicable to HCT/Ps (e.g., current good tissue practice requirements), which are not addressed in the draft guidance.

We previously have issued a separate draft guidance document entitled “Guidance for Industry: Preventive Measures to Reduce the Possible Risk of Transmission of Creutzfeldt-Jakob Disease (CJD) and Variant Creutzfeldt-Jakob Disease (vCJD) by Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)” dated June 2002. We intend to issue a single final guidance document that incorporates our guidance on CJD and vCJD with the substance of this document into a final guidance on donor eligibility.

The draft guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The draft guidance document, when finalized, will represent the agency’s current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to

bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 USC 3501–3520). The collection(s) of information addressed in the guidance document has been submitted to OMB for review in accordance with the PRA under the regulations governing donor-eligibility determination for donors of HCT/Ps (part 1271).

III. Comments

The draft guidance is being distributed for comment purposes only and is not intended for implementation at this time. Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding the draft guidance. Submit written or electronic comments to ensure adequate consideration in preparation of the final guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. A copy of the draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either <http://www.fda.gov/cber/guidelines.htm> or <http://www.fda.gov/ohrms/dockets/default.htm>.

Dated: 4/27/04

April 27, 2004.

Jeffrey Shuren

Jeffrey Shuren,
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